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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,770	07/01/2003	James E. Brewer	A03P1047	4998

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
GEDEON, BRIAN T	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,770	BREWER ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-120* is/are rejected.

7)☒ Claim(s) *8, 9, and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 25 May 2006, with respect to the rejection(s) of claim(s) 1-7, 10-12, and 14-20 under US Patent 6,738;669 to Sloman et al. in view of US Patent 6,976,967 to Dahl et al. and of claim 13 under US Patent 6,738,669 to Sloman et al. in view of US Patent 6,976,967 to Dahl et al. further in view of US Patent 6,438,408 to Mulligan et al. have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of US Patent 6,738,669 to Sloman et al. in view of US Patent 5,662,108 to Budd et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-7, 10-12 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman et al. (US Patent no. 6,738,669) in view of Budd et al. (US Patent no. 5,662,108).

In regards to claims 1 and 15, Sloman et al. discloses an implantable medical device 10 for multichamber cardiac stimulation that delivers an electrical pulse to one of the chambers of the patient's heart, col 7 lines 47-63. The electrical signals can be

delivered to any chamber of the heart, col 11 lines 39-42. Upon delivery of an electrical pulse, far-field sensing occurs, col 11 lines 53-58. For example, if right ventricle stimulation occurs, far-field sensing by a combination of electrodes may occur in the right atrium lead 20 or coronary sinus lead 24, col 12 lines 17-21. Budd et al. discloses an electrophysiology mapping system with a monitoring catheter 14 placed into the heart 16 to generate and display electrical activity of the heart. The catheter 14 has a pair of electrodes shown as a delivery electrode 60 and reference electrode 62, col 5 lines 13-16. A Wall Surface Generation process (WSGP) uses the electrode pair to generate and measure currents throughout the heart, col 5 lines 66-67 through col 6 lines 1-33. THE WSGP can be used to present the full three-dimensional geometry of a heart chamber, col 12 lines 60-67 (and Figures 5 and 9). Therefore it would have been obvious to one of ordinary skill in the art to use the catheter described by Budd et al. with the methods and apparatus disclosed by Sloman et al. in order to a visual map of the heart's anatomy as well as electrical activity in order to better asses the need for therapy, such as ablation techniques.

In regards to claim 2, Sloman et al. states that the sensing and stimulating electrodes may have a unipolar configuration, col 8 lines 8-12.

In regards to claim 3, Sloman et al. shows that stimulation can take place in the right ventricle, col 12 lines 17-21.

In regards to claim 4, Sloman et al. discloses several leads for placement in the right ventricle with a ring electrode, col 6 lines 47-60.

In regards to claim 5, Sloman et al. teaches that there can be a sensing electrode placed in the superior vena cava, col 6 lines 47-60.

In regards to claim 6, Sloman et al discloses that sensing can occur in a chamber, col 6 lines 47-60, and can occur in any of the four chambers of the heart, col 8 lines 13-17 and col 12 lines 17-21.

In regards to claim 7, Sloman et al. shows that sensing can occur in a unipolar fashion, col 12 lines 17-21.

In regards to claims 10-12, Sloman et al. substantially describes the claimed invention except for the steps of determining a ventricular volume or a ventricular distance. Budd et al. teaches that the moving of the heart wall (e.g., expanding and contracting) cause the applied electric field to be modified, col 1 lines 62-63. Budd et al. monitor the location of the interior wall of the heart in order to assess modifications to the electrophysiological properties of the heart. Therefore it would have been obvious to one of ordinary skill in the art to combine the above references so that optimal electrical therapy can be applied to locations in the beating heart.

In regards to claim 14, Sloman et al. states that after a stimulation pulse is delivered to a portion of the heart, the far-field sensing is used in conjunction with other processes to determine if capture in that portion of the heart was successful. If it was determined that capture was unsuccessful, another stimulation pulse is then applied, col 13 lines 26-37.

In regards to claim 16, Sloman et al. substantially describes the claimed invention including a battery for power 110, and stimulation leads 30 having a tip 32 and ring electrode 34, col 6 lines 46-60.

In regards to claim 17, the sensing means of Sloman et al. includes a sensing circuit 82 and 84 coupled to sensing leads 20 and 30, col 8 lines 13-17. Each lead has a plurality of electrodes, col 6 lines 20-60.

In regards to claim 18, the implantable stimulation device 10 has a programmable microcontroller 60 that controls stimulation therapy and processes all incoming signals, col 7 lines 36-47.

In regards to claim 19, Sloman et al. discloses an implantable device 10 with a housing 40, referred to as the "case" or "can", and it may act as the return electrode for all unipolar modes, col 7 lines 5-19. The device has a plurality of leads 20, 24, and 30 connected to the device and is implantable within many structures of the heart, col 6 lines 19-27. Pulse generators 70 and 72 generate stimulation pulses for delivery to the implantable leads, 20, 24, and 30, col 7 lines 48-63. Sensing circuits 82 and 84 are used upon delivery of an electrical pulse, for far-field sensing occurs, col 8 lines 13-17 and col 11 lines 53-58. For example, if right ventricle stimulation occurs, far-field sensing by a combination of electrodes may occur in the right atrium lead 20 or coronary sinus lead 24, col 12 lines 17-21. Budd et al. discloses an electrophysiology mapping system with a monitoring catheter 14 placed into the heart 16 to generate and display electrical activity of the heart. The catheter 14 has a pair of electrodes shown as a delivery electrode 60 and reference electrode 62, col 5 lines 13-16. A Wall Surface

Generation process (WSGP) uses the electrode pair to generate and measure currents throughout the heart, col 5 lines 66-67 through col 6 lines 1-33. THE WSGP can be used to present the full three-dimensional geometry of a heart chamber, col 12 lines 60-67 (and Figures 5 and 9). Therefore it would have been obvious to one of ordinary skill in the art to use the catheter described by Budd et al. with the methods and apparatus disclosed by Sloman et al. in order to a visual map of the heart's anatomy as well as electrical activity in order to better asses the need for therapy, such as ablation techniques.

In regards to claim 20, Sloman et al. possesses one or more ventricular leads, col 6 lines 13-18. Lead 24 is configured for the left ventricle, col 6 lines 40-35.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloman et al. (US Patent no. 6,738,669) in view of Budd et al. (US Patent no. 5,662,108) and further in view of Mulligan et al. (US Patent no. 6,438,408).

3. Sloman et al. in view of Budd et al. substantially describe the claimed invention except for relating the change in cardiac dimensions to congestive heart failure. Mulligan et al. uses pairs of impedance electrodes 170, 172, 174, 176 to measure the heart chamber volume, col 16 lines 28-49. The methods and apparatus of Mulligan et al. are believed to benefit patient's suffering from heart failure, including congestive heart failure, col 28 lines 2-4. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to monitor the physical geometry of the heart in order to better assess and electrically treat cardiac abnormalities.

Allowable Subject Matter

4. Claims 8, 9, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

5. This Office action is made NON-FINAL.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brewer et al. (US Patent no. 7,003,348) disclose an implantable medical device monitoring cardiac geometry for diagnostics and therapy. Ben-Haim et al. (US Patent no. 6,891,091) discloses a method and apparatus for rapidly generating an electrical map of a chamber of the heart utilizing a catheter. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian T. Gedeon
Patent Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG